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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,623	09/14/2000	Dennis CheroK	D0188/7125	8712

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Jason M Honeyman
Wolf Greenfield & Sacks P C
600 Atlantic Ave
Boston, MA 02210

EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/661,623

Applicant(s)

CHEROK ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 29-45 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-21, 29-45 and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6-22-07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 6-22-07 have been fully considered but they are not persuasive. Applicant contends it would not have been obvious to combine the teachings of Ory et al. with the Meier device because each device has different intended purposes, and that the teachings of Ory et al. would not maintain protection across the entire thickness of the repair fabric peripheral edge, and would require absorbable materials. Examiner respectfully disagrees. First, each device is directed toward tissue wound defects. As shown by WO 00/16822 (provided in Applicant's IDS on 6/22/07) at page 14 line 25 – page 15 line 28, one of ordinary skill in tissue repair would readily look to external and internal tissue repair structures. Additionally, Meier disclose the crown 12 as comprising an inert thermoplastic resin (col. 2, lines 69 through col. 3 line 16) that covers the entire thickness of the porous layer (figure 4). Meier is not clear that this inert material is necessarily adhesion resistant, although "inert" implies the structure would not promote adhesions. Ory et al. is provided in the rejection to teach the modification of the crown such that it would be adhesion resistant in order to protect the edge, which would be achieved by non-porous features of the material (see Ory et al. lines 26-30 of col. 4) rather than absorbable features as suggested by Applicant. Furthermore, as Meier already teach "maintaining the peripheral barrier across the entire thickness of the outer peripheral edge" (Meier, figure 4), Ory et al. need not teach this feature.

Regarding the tapered feature, figure 4 clearly show each element (12,14,15) having a tapered periphery.

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Regarding melting and resolidifying, Meier clearly disclose fusion which includes melting and resolidifying.

Regarding claim 54, the bite region is formed by sutures 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 14-16, 18, 20, 54, 58 are rejected under 35 U.S.C. 102(a) as being anticipated by Orgill et al. WO 00/16822.

Orgill et al. disclose a tissue repair prosthesis comprising polypropylene repair fabric completely surrounded by a barrier layer and peripheral barrier as claimed (see example p16). Sutures are disclosed at page 14 which would connect the layers, reinforced repair fabric layer is disclosed at page 8-9 (multiple layers).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-7,14-17,20,29-35,37-44,54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier US PN 3,416,524 in view of Ory et al. US PN 6,075,180.

Meier disclose in figures 1, 2, and 4 an implantable prosthesis for repairing tissue defects comprising layer of repair fabric 14, barrier layer 15, and peripheral barrier 12. The peripheral barrier 12, barrier layer 15, and fabric 14 are shown as tapering towards the outer edge of the device in figure 4. Lines 55-70 of col. 1 describe the fabric layer comprising polypropylene. Meier further disclose (lines 10-16 of col. 3) that peripheral barrier may be melted and resolidified. However, Meier fails to expressly disclose the peripheral barrier 12 as inhibiting formation of adhesions with tissue or organs thereto.

Ory et al. disclose in figure 1 an implantable prosthesis for repairing tissue defects comprising layer of repair fabric 4 and barrier layer 3, wherein the peripheral edge of the repair fabric is adapted to inhibit the formation of adhesions by peripheral barrier (extended region of barrier layer 3, described at lines 26-30 of col. 4) which protects the peripheral edge from forming adhesions with adjacent organs.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the peripheral barrier of Meier to comprise a material that is adhesion resistant, as taught by Ory, in order to inhibits the formation of adhesions with adjacent organs after implantation.

Claims 18,19,21,36,45,59 as being unpatentable over Meier US PN 3,416,524 in view of Ory et al. US PN 6,264,702 as applied to claims 1-7,14-17,20,29-35,37-44,54-58 above, and further in view of Sharber US PN 6,075,180.

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Meier, as modified by Ory et al. meet the limitations of claims 18,19,21,36,45,59 as described above, but lacks the express written disclosure of the using PTFE material for the sutures or barrier layer. Sharber teach in lines 54-67 of col. 1 it is well known to use PTFE suture and ePTFE barrier layer for hernia repair surgery in order to reduce negative reactions after implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the device disclosed by Meier, as modified by Ory et al., to include PTFE suture and ePTFE barrier layer as taught by Sharber in order to reduce negative reactions after implantation.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6-22-07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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